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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.              | CONFIRMATION NO.       |
|--|-------------|----------------------|----------------------------------|------------------------|
| 10/501,671   | 06/28/2005  | Fumihide Nishio      | 8065-1006                        | 9947                   |
| <div>466      7590      09/04/2007</div> <div>YOUNG &amp; THOMPSON<br/>745 SOUTH 23RD STREET<br/>2ND FLOOR<br/>ARLINGTON, VA 22202</div> |             |                      |                                  |                        |
|  |             |                      | EXAMINER<br>MACAULEY, SHERIDAN R |                        |
|  |             |                      | ART UNIT<br>1651                 | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>09/04/2007          | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/501,671

Applicant(s)

NISHIO, FUMIHIDE

Examiner

Sheridan R. MacAuley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-18, drawn to a method of stabilizing foaming of a high-concentrated soluble thrombomodulin-containing solution. *Note that election of this group will also require an election of species. See species election requirement below.*

Group II, claim(s) 19, drawn to a foam-inhibitor for a high concentrated soluble thromomodulin-containing solution. *Note that election of this group will also require an election of species. See species election requirement below.*

Group III, claim(s) 20-34, drawn to a soluble thrombomodulin-containing freeze-dried preparation or kit preparation thereof. *Note that election of this group will also require an election of species. See species election requirement below.*

Group IV, claim(s) 35-37, drawn to a method of stabilizing soluble thrombomodulin in a soluble thrombomodulin freeze-dried preparation. *Note that election of this group will also require an election of species. See species election requirement below.*

2. The inventions listed as Groups I through IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There is no technical feature common to Groups I through IV, and the technical feature common to Groups I, III, IV is a soluble thrombomodulin. However, a soluble thrombomodulin is known in the art, as taught by EP1029548 (abstract; reference cited in IDS). Therefore, there is no special technical feature which makes a contribution over the prior art.

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3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- A. For Group I, election is required of the three elements of the method set forth in claim 1. Applicant may elect method element (a) (i.e. "allowing the presence of at least one compound selected from..."), method element (b), method element (c), or a specific combination thereof.
- B. For Group I, if applicant elects method element (a) or a combination comprising method element (a), election is required of the compounds recited therein. Applicant may elect a nonionic surfactant, benzyl alcohol or chlorobutanol (recited in claims 2-4 and 10-14)
- C. For Group I, election is required of the various combinations recited in claim 10. Applicant may elect combination (1) (i.e. "a combination containing two of glutamic acid or a salt thereof and mannitol"), combination (2), combination (3), combination (4), or a specific combination thereof.
- D. For Group I, election is required of the various peptide sequences recited in claims 16-18. Applicant may elect from the following SEQ ID NOs: 3 (recited in claim 16), 7 (recited in claim 16), 4 (recited in claim 17), 8 (recited in claim 17), 1 (recited in claim 18) and 5 (recited in claim 18).
- E. For Group II election is required of the compounds recited in claim 19.  
Applicant may elect a nonionic surfactant, benzyl alcohol or chlorobutanol.

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- F. For Group III, election is required of the three elements set forth in claims 20, 25 and 26. Applicant may elect element (a) (i.e. "that at least one compound selected from..."), method element (b), method element (c), or a specific combination thereof.
- G. For Group III, if applicant elects method element (a) or a combination comprising element (a), election is required of the compounds recited therein. Applicant may elect a nonionic surfactant, benzyl alcohol or chlorobutanol (recited in claims 20, 21, 24-26, 29 and 30).
- H. For Group III, election is required of the various combinations recited in claims 23-26. Applicant may elect combination (1) (i.e. "a combination containing two of glutamic acid or a salt thereof and mannitol"), combination (2), combination (3), combination (4), or a specific combination thereof.
- I. For Group III, election is required of the various peptide sequences recited in claims 32-34. Applicant may elect from the following SEQ ID NOs: 3 (recited in claim 32), 7 (recited in claim 32), 4 (recited in claim 33), 8 (recited in claim 33), 1 (recited in claim 34) and 5 (recited in claim 34).
- J. For Group IV, election is required of the various combinations recited in claim 35. Applicant may elect combination (1) (i.e. "a combination containing two of glutamic acid or a salt thereof and mannitol"), combination (2), combination (3), combination (4), or a specific combination thereof.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply

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must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species as set forth above.

The following claim(s) are generic: No claims are generic for species groups A, B, E, F, G and J; claim 1 is generic for species groups C and D; and claim 20 is generic for species groups H and I.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: : The technical feature common to the species groups is a soluble thrombomodulin. However, a soluble thrombomodulin is known in the art, as taught by EP1029548 (abstract; reference cited in IDS). Therefore, the species set forth above do not share a special technical feature that makes a contribution over the prior art.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan R. MacAuley whose telephone number is (571) 270-3056. The examiner can normally be reached on Mon-Thurs, 7:30AM-5:00PM EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SRM

/Ruth A Davis/  
Primary Examiner, AU 1651